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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/972,830	10/05/2001	Michael I. Nerenberg	267/301	3809

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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 11/20/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/972,830

Applicant(s)

NERENBERG ET AL.

Examiner

BJ Forman

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-18 and 20-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-18 and 20-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I (Claims 10-18 and 20-27) and cancellation of Claim 19 in Paper No. 8 is acknowledged.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 10-18 and 20-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 10-18 are indefinite in Claim 10 for the recitation "electrodes associated with each sensor pad" because "associated with" is a non-specific relational phrase. Therefore, the relationship between the electors and sensor pad is undefined and it is unclear whether the relationship is physical, functional, one-to-one, and/or operational. It is suggested that Claim 1 be amended to define the relationship.

b. Claims 10-18 are indefinite in Claim 10 for the recitations "probes are capable of hybridizing to a target nucleic acid sequence" and "polynucleotides are capable of participating in a strand displacement amplification reaction." because it is unclear what structural and/or compositional limitations are being imposed upon the probes and polynucleotides. It is

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suggested that Claim 1 be amended to define the structural and/or compositional limitations of the probes and polynucleotides.

c. Claims 15 and 25 are each indefinite for the recitation "the sensor pads are capable of exerting a force of about 5pN" because it is unclear what structural limitations are being imposed upon the sensor pads.

d. Claims 16 and 17 are each indefinite for the recitation "the sensor" because the recitation lacks proper antecedent basis in Claim 10 which recites "micro sensor" and "sensor pads". Therefore, it is unclear which sensor is being defined. It is suggested that Claims 16 and 17 be amended provide proper antecedent basis.

e. Claims 20-28 are indefinite in Claim 20 for the recitation "electrodes associated with each sensor pad" because "associated with" is a non-specific relational phrase. Therefore, the relationship between the electrodes and sensor pad is undefined and it is unclear whether the relationship is physical, functional, one-to-one, and/or operational. It is suggested that Claim 20 be amended to define the relationship.

f. Claims 20-28 are indefinite in Claim 20 for the recitations "probes are capable of hybridizing to a target nucleic acid sequence" and "polynucleotides are capable of participating in a strand displacement amplification reaction." because it is unclear what structural and/or compositional limitations are being imposed upon the probes and polynucleotides. It is suggested that Claim 20 be amended to define the structural and/or compositional limitations of the probes and polynucleotides.

g. Claims 26 and 27 are each indefinite for the recitation "the sensor" because the recitation lacks proper antecedent basis in Claim 20 which recites "micro sensor" and "sensor pads". Therefore, it is unclear which sensor is being defined. It is suggested that Claims 26 and 27 be amended provide proper antecedent basis.

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Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 10-13, 17, 20-23 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al (U.S. Patent No. 6,184,029, filed 27 January 1999) and Tyagi et al (U.S. Patent No. 5,759,773, filed 24 February 1995).

Regarding Claim 10, Wilding et al teach a device for detecting a target molecule in a sample solution comprising a flow cell having channels for receiving a flowable medium (i.e. covered substrate, Column 10, lines 25-32 and Fig. 1), wherein the flow cell has one or more micro sensor (i.e. chamber) for manipulation and/or detection of magnetic beads (Column 10, lines 61-67 and Column 11, line 50-Column 12, line 9 and Fig. 8) wherein the sensors have sensor pads and electrodes associated with each sensor pad (Column 12, lines 4-9 and Column 15, line 62-Column 16, line 4) and wherein the sensor pads comprise attached polynucleotide probes (i.e. the capture reagent is immobilized in the chamber and the analyte is captured using a sandwich assay and wherein the device is useful for strand displacement amplification (SDA), Column 14, lines 42-46 and Column 22, lines 31-35) and a population of magnetic beads within the flow cell wherein each of the microbeads comprises an attached first set of attached polynucleotides comprising a target nucleic acid sequence (i.e. capture probe, Column 21, lines 5-16 and 31-36). Wilding et al teach the device is useful for SDA, but they do not teach SDA-specific sequences. However, capture probes and SDA were well known in the art at the time the claimed invention was made as taught by Tyagi et al (Column 4, lines 45-59) and they teach preferred capture probes on beads comprise a target specific sequence and a

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restriction endonuclease recognition sequence (Column 21, lines 53-67) wherein the target-probe complex is released from the bead by incubation with the restriction enzyme.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the capture probe of Wilding et al by incorporating a restriction site into the capture probe as taught by Tyagi et al wherein probe-target complexes are released by incubation with the restriction enzyme as taught by Tyagi et al (Column 21, lines 53-67) for the expected benefits of increased sensitivity and decreased background signal as taught by Tyagi et al (Column 4, lines 15-44).

Regarding Claim 11, Wilding et al teach the device wherein at least one of the magnetic beads further comprises an attached second set of polynucleotides i.e. the device comprises multiple immobilization chamber as illustrated in Fig 8 wherein the analyte (target) is captured (Column 4, lines 25-41 and Column 14, lines 27-46).

Regarding Claim 12, Wilding et al teach the device wherein various (i.e. different) targets are captured and detected (Column 4, lines 25-30) which suggest that different capture probes are utilized to capture the different targets. Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to attach different capture probes to different sub-populations of beads for the obvious benefit of capturing different targets as suggested by Wilding et al (Column 4, lines 25-30).

Regarding Claim 13, Wilding et al teach the device wherein various (i.e. different) targets are captured and detected (Column 4, lines 25-30) but they are silent regarding the number of different sub-populations. However, the courts have stated that "Mere duplication of parts has no patentable significance unless new and unexpected result is produced" (see *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960) and MPEP, 2144.05 VI). Therefore, absent unexpected results, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide the device of Wilding et al with 20 sub-populations of magnetic beads for thereby providing the means to detect 20 different analytes in a single device. The

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skilled practitioner in the art would have been motivated to detect 20 different analytes because the device would have multiple diagnostic applications i.e. it would be useful for detecting 20 different clinically important sequences.

Regarding Claim 17, Wilding et al teach the device wherein various (i.e. different) targets are captured and detected on sensors (Column 4, lines 25-30) but they are silent regarding the number of different sensors. However, the courts have stated that "Mere duplication of parts has no patentable significance unless new and unexpected result is produced" (see *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960) and MPEP, 2144.05 VI). Therefore, absent unexpected results, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide the device of Wilding et al with between 64 and 4096 individual sensors thereby providing the means to detect at least 64 different analytes in a single device. The skilled practitioner in the art would have been motivated to detect at least 64 different analytes because the device would have multiple diagnostic applications i.e. it would be useful for detecting at least 64 different clinically important sequences.

Regarding Claim 20, Wilding et al teach a device for detecting a target molecule in a sample solution comprising a flow cell having channels for receiving a flowable medium (i.e. covered substrate, Column 10, lines 25-32 and Fig. 1), wherein the flow cell comprise at least one microsensor for manipulation and/or detection of magnetic beads (Column 10, lines 61-67 and Column 11, line 50-Column 12, line 9) wherein the sensors have sensor pads and electrodes associated with each sensor pad (Column 12, lines 4-9 and Column 15, line 62-Column 16, line 4) and wherein the sensor pads comprise attached polynucleotide probes (i.e. the capture reagent is immobilized in the chamber and the analyte is captured using a sandwich assay and wherein the device is useful for strand displacement amplification (SDA), Column 14, lines 42-46 and Column 22, lines 31-35) and a population of magnetic beads within the flow cell wherein each of the microbeads comprises an attached first set of attached polynucleotides comprising a target nucleic acid sequence (i.e. capture probe, Column 21, lines

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5-16 and 31-36). Wilding et al teach the device is useful for SDA, but they do not teach SDA-specific sequences. However, capture probes and SDA were well known in the art at the time the claimed invention was made as taught by Tyagi et al (Column 4, lines 45-59) and they teach preferred capture probes comprise a target specific sequence and a restriction endonuclease recognition sequence (Column 21, lines 53-67) wherein the target-probe complex is released by incubation with the restriction enzyme.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the capture probe of Wilding et al by incorporating a restriction site into the capture probe as taught by Tyagi et al wherein probe-target complexes are released by incubation with the restriction enzyme as taught by Tyagi et al (Column 21, lines 53-67) for the expected benefits of increased sensitivity and decreased background signal as taught by Tyagi et al (Column 4, lines 15-44).

Regarding Claim 21, Wilding et al teach the device wherein at least one of the magnetic beads further comprises an attached second set of polynucleotides i.e. the device comprises multiple immobilization chamber as illustrated in Fig 8 wherein the analyte (target) is captured (Column 4, lines 25-41 and Column 14, lines 27-46).

Regarding Claim 22, Wilding et al teach the device wherein various (i.e. different) targets are captured and detected (Column 4, lines 25-30) which suggest that different capture probes are utilized to capture the different targets. Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to attach different capture probes to different sub-populations of beads for the obvious benefit of capturing different targets as suggested by Wilding et al (Column 4, lines 25-30).

Regarding Claim 23, Wilding et al teach the device wherein various (i.e. different) targets are captured and detected (Column 4, lines 25-30) but they are silent regarding the number of different sub-populations. However, the courts have stated that "Mere duplication of parts has no patentable significance unless new and unexpected result is produced" (see *In re Harza*,

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274 F.2d 669, 124 USPQ 378 (CCPA 1960) and MPEP, 2144.05 VI). Therefore, absent unexpected results, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide the device of Wilding et al with 20 sub-populations of magnetic beads for thereby providing the means to detect 20 different analytes in a single device. The skilled practitioner in the art would have been motivated to detect 20 different analytes because the device would have multiple diagnostic applications i.e. it would be useful for detecting 20 different clinically important sequences.

Regarding Claim 27, Wilding et al teach the device wherein various (i.e. different) targets are captured and detected on sensors (Column 4, lines 25-30) but they are silent regarding the number of different sensors. However, the courts have stated that "Mere duplication of parts has no patentable significance unless new and unexpected result is produced" (see *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960) and MPEP, 2144.05 VI). Therefore, absent unexpected results, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide the device of Wilding et al with between 64 and 4096 individual sensors thereby providing the means to detect at least 64 different analytes in a single device. The skilled practitioner in the art would have been motivated to detect at least 64 different analytes because the device would have multiple diagnostic applications i.e. it would be useful for detecting at least 64 different clinically important sequences.

6. Claims 14, 15, 18, 24, 25 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al (U.S. Patent No. 6,184,029, filed 27 January 1999) and Tyagi et al (U.S. Patent No. 5,759,773, filed 24 February 1995) as applied to Claims 10 and 20 above and further in view of Wilding et al(b) (U.S. Patent No. 5,955,029, filed 12 March 1996).

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Regarding Claim 14, Wilding et al teach the device wherein the beads are magnetic (Column 10, lines 61-67) but they do not specifically teach the magnetic beads comprise iron oxide. However, ferromagnetic beads were well known in the art at the time the claimed invention was made as they teach in their '029 patent. Specifically, Wilding et al(b) teach a similar device comprising a flow cell having channels and a population of magnetic beads wherein the beads comprise iron oxide (Column 13, lines 65-67). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the well known ferromagnetic beads of Wilding et al(b) to the magnetic beads of Wilding et al(a) based on their preferred use, availability and positive results as suggested by Wilding et al(b) (Column 13, lines 65-67).

Regarding Claim 15, Wilding et al teach the device comprising sensor pads i.e. chamber, but as stated above, it is unclear what structural limitations "are capable of exerting a force of about 5 pN on the magnetic beads" imposes. For purposes of examination, the claim is interpreted as the device exerts magnetic force. The device of Wilding et al(b) exerts a magnetic force. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the device of Wilding et al by adding the magnet of Wilding et al(b) for the expected benefit of moving and transporting the magnetic beads within the device for simple detection and/or collection as taught by Wilding et al(b).

Regarding Claim 18, Wilding et al teach the device comprising magnetic beads (Column 10, lines 61-67) but they do not specifically teach the device further comprises a magnet functionally positioned for sweeping non-specifically bound magnetic beads from the surface. However, functionally positioned magnets were well known in the art as they teach in their '029 patent. Specifically, Wilding et al(b) teach their similar device wherein a magnet is positioned to transport the magnetic beads (Column 13, line 65-Column 14, line 13). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the device of Wilding et al by adding the magnet of Wilding et al(b) for the

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expected benefit of moving and transporting the magnetic beads within the device for simple detection and/or collection as taught by Wilding et al(b). The recitation “for sweeping non-specifically bound magnetic beads from the surface” is functional languages which does not describe structural limitations of the device.

The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP, 2114).

A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Regarding Claim 24, Wilding et al teach the device wherein the beads are magnetic (Column 10, lines 61-67) but they do not specifically teach the magnetic beads comprise iron oxide. However, ferromagnetic beads were well known in the art at the time the claimed invention was made as they teach in their '029 patent. Specifically, Wilding et al(b) teach a similar device comprising a flow cell having channels and a population of magnetic beads wherein the beads comprise iron oxide (Column 13, lines 65-67). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the well known ferromagnetic beads of Wilding et al(b) to the magnetic beads of Wilding et al(a) based on their preferred use, availability and positive results as suggested by Wilding et al(b) (Column 13, lines 65-67).

Regarding Claim 25, Wilding et al teach the device comprising sensor pads i.e. chamber, but as stated above, it is unclear what structural limitations “are capable of exerting a force of about 5 pN on the magnetic beads” imposes. For purposes of examination, the claim

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is interpreted as the device exerts magnetic force. The device of Wilding et al(b) exerts a magnetic force. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the device of Wilding et al by adding the magnet of Wilding et al(b) for the expected benefit of moving and transporting the magnetic beads within the device for simple detection and/or collection as taught by Wilding et al(b).

Regarding Claim 28, Wilding et al teach the device comprising magnetic beads (Column 10, lines 61-67) but they do not specifically teach the device further comprises a magnet functionally positioned for sweeping non-specifically bound magnetic beads from the surface. However, functionally positioned magnets were well known in the art as they teach in their '029 patent. Specifically, Wilding et al(b) teach their similar device wherein a magnet is positioned to transport the magnetic beads (Column 13, line 65-Column 14, line 13). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the device of Wilding et al by adding the magnet of Wilding et al(b) for the expected benefit of moving and transporting the magnetic beads within the device for simple detection and/or collection as taught by Wilding et al(b). The recitation "for sweeping non-specifically bound magnetic beads from the surface" is functional languages which does not describe structural limitations of the device.

7. Claims 16 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al (U.S. Patent No. 6,184,029, filed 27 January 1999) and Tyagi et al (U.S. Patent No. 5,759,773, filed 24 February 1995) as applied to Claims 10 and 20 above and further in view of Hurst, Jr. et al (U.S. Patent No. 6,147,022, filed 14 April 1998).

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Regarding Claim 16, Wilding et al teach the device comprises magnetic beads (Column 10, lines 61-67) but they do not teach the device comprises pseudo spin-valve material. However, pseudo spin-valve material was well known in the art at the time the claimed invention was made as taught by Hurst et al who teach that pseudo spin-valve material simplifies the design of magnetic elements (Abstract). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the pseudo spin-valve material to the magnetic elements of Wilding et al for the obvious benefits of simplicity as taught by Hurst et al (Abstract).

Regarding Claim 26, Wilding et al teach the device comprises magnetic beads (Column 10, lines 61-67) but they do not teach the device comprises pseudo spin-valve material. However, pseudo spin-valve material was well known in the art at the time the claimed invention was made as taught by Hurst et al who teach that pseudo spin-valve material simplifies the design of magnetic elements (Abstract). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the pseudo spin-valve material to the magnetic elements of Wilding et al for the obvious benefits of simplicity as taught by Hurst et al (Abstract).

Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Patent Examiner
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October 25, 2002